

PCT

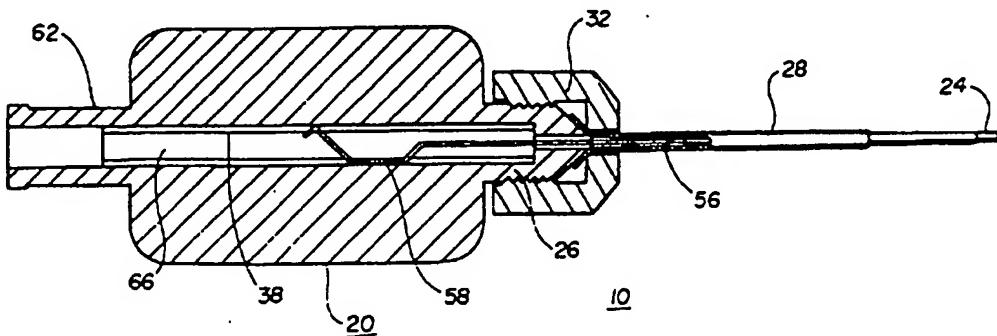
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ :	A1	(11) International Publication Number: WO 97/13455 (43) International Publication Date: 17 April 1997 (17.04.97)
(21) International Application Number:	PCT/US96/16004	(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date:	3 October 1996 (03.10.96)	
(30) Priority Data:	08/541,147 11 October 1995 (11.10.95) US	Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(71) Applicant:	MICRO THERAPEUTICS, INC. [US/US]; 1062-F Calle Negocio, San Clemente, CA 92673 (US).	
(72) Inventors:	WALKER, Blair, D.; 275 Esperanza Avenue #304, Long Beach, CA 90802 (US). EVANS, Scott, M.; 1252 Country Hills Drive, Santa Ana, CA 92705 (US).	
(74) Agent:	BREIMAYER, Joseph, F.; Breimayer Law Office, Suite 206, 1221 Nicollet Mall, Minneapolis, MN 55403 (US).	

(54) Title: INFUSION GUIDEWIRE HAVING FIXED CORE WIRE AND FLEXIBLE RADIOPAQUE MARKER



(57) Abstract

An infusion guidewire (10) or catheter having an integral, tapered core wire within an infusion lumen formed of the aligned lumens of a proximal connector housing a proximal inner sheath (24) in a proximal body portion and a distal wire coil in a distal body portion. The core wire (56) is fixed to the connector housing (20) and extends over the proximal inner sheath and the distal coil. A plurality of infusion side holes (58) are formed in a distal infusion segment of the outer sheath in fluid communication with the infusion lumen. At the junction (36) of the proximal inner sheath (24) and the distal wire coil, a radiopaque wire coil (40) of a material having a higher radiopacity than the distal wire coil is wound into spacings between adjacent turns of the proximal wire coil.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Larvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

**INFUSION GUIDEWIRE HAVING FIXED CORE WIRE
AND FLEXIBLE RADIOPAQUE MARKER**

5 The present invention relates to medical catheters and guidewires commonly used in the placement of catheters in a patient's vascular system, and particularly to infusion wires that can be used either as a guidewire or an infusion catheter.

10 Medical catheters and guidewires are devices that can be navigated through narrow body passages, typically blood vessels, until the distal end section is in a desired location. Guidewires are typically used for introduction of a catheter over the guidewire.

15 Cardiovascular guidewires typically have a solid core wire and are dimensioned to be received within a catheter lumen as the catheter is advanced over the guidewire. One very common guidewire construction has an elongated, flexible, helical coil having a proximal end and a distal end, the latter being inserted into the patient's vascular system. The internal core wire typically extends through the coil lumen with the proximal and distal ends of the core wire attached to the proximal and distal ends of the coil. A physician controls the advancement and resulting position of the distal end of the guidewire by manipulations performed at the proximal end outside the body. Then, 20 a catheter is advanced over the guidewire, which may be left in place or withdrawn during a procedure using the guidewire.

25 In order to advance the catheter over the guidewire, it must be uniform in outer diameter or have only step down diameter reductions and no diameter increases. In addition, both catheters and guidewires are preferably constructed with radiopaque markers that are have greater radiopacity and hence higher visibility under fluoroscopy than the bulk of the elongated catheter or guidewire body. These markers allow the physician to visualize the location of the distal end and/or intermediate point(s) along the elongated body within the patient's body. When both the guidewire and the catheter are provided with such markers, care must be taken that they are not so long on one or both

-2-

device that they mask one another or are confusing. In this regard, it may not be desirable to make the entire wire coil in the distal segment or portion of a high density radiopaque material, because its bright appearance under fluoroscopy would mask any radiopaque marker(s) on the catheter being introduced over it.

5 Some guidewires are constructed of wire coil defining a guidewire lumen with an outer sheath surrounding or within the wire coil and are adapted for use both as guidewires and as infusion catheters as disclosed, for example, in U.S. Patent Nos. 5,178,158, 5,184,627, and 5,211,636. They are provided with either a distal axial open end hole or a closed distal end with infusion side holes and a lumen for conveying 10 infusion fluids or body fluids between the proximal end and the end hole or side holes.

In order to operate as a guide wire and be advanced through a tortuous vascular pathway to a desired infusion site, it is necessary that the overall outer diameter be as small as possible and that the construction provide for ease of advancement and excellent steerability or torqueability from the manipulated proximal end to the distal end thereof.

15 Moreover, the construction typically requires increasing flexibility in the intermediate and distal sections. In order to provide adequate infusion capabilities, the side wall thickness has to be minimized to maximize potential infusion volume. The side wall construction also has to withstand high fluid pressures during infusion.

In use, because of the narrow gauge, flexibility and column strength, the distal 20 portion of an infusion guidewire can be advanced to a desired site in a blood vessel. Then, the physician can advance a catheter over the infusion guidewire to the site. Depending on the design, the physician can remove the infusion guidewire from the catheter lumen or leave it in place while conducting a procedure with the catheter. Drugs or agents can be infused from the proximal end of the infusion guidewire, through 25 the lumen, and out through the distal end lumen opening or through side holes in the sheath or through spaces between exposed turns of distal wire coil, if any, during or following the procedure using the catheter. Alternatively, distal blood pressure may be monitored through a fluid column in the lumen.

A further infusion guidewire is disclosed in U.S. Patent No. 5,322,508 wherein a 30 partial length core wire is attached at the distal end of a metal hypotube guidewire body and extends distally within a wire coil also attached at the distal end of the hypotube.

Hypotube construction without a full length core wire may provide a maximal size cross-

section, infusion lumen that may accommodate a relatively high infusion flow rate. However, the constriction at the attachment to the distal core wire extension before the distal infusion side holes negates the advantage imparted by the unobstructed hypotube lumen. Moreover, hypotube does not provide for a 1:1 torque transmission down the 5 length of the guidewire during twisting or rotational advancement.

Currently, there are two types of clinically used infusion guidewires, one having a closed end of the type disclosed in the '627 patent and another having an open end of the type disclosed in the '158 patent and sometimes referred to as a "convertible wire". The '158 and '627 patents describe infusion wires and convertible wires having full 10 length, coiled wire bodies within outer sheathes with constant diameter infusion lumens. In each case, the proximal sections have a polyimide tube between the wire coil and the outer sheath to strengthen that section and allow increased infusate pressure. The convertible wire disclosed in the '158 patent delivers the infusate through a distal end hole of the infusion lumen. The infusion wire disclosed in the '627 patent has a closed 15 distal end and a plurality of infusion side holes cut in the outer sheath which covers the wire coil. In both cases, the removable core wire supplies sufficient column strength for steerability as the convertible wire or infusion wire is advanced to the treatment site.

In use of these infusion wires and convertible wires, when infusion therapy is desired, the core wire must be completely removed, since it occupies the bulk of the 20 infusion lumen and would increase flow resistance and decrease flow rate dramatically were it left in place. The handling of this core wire is bothersome to many physicians. In addition, because of the full length coil construction (and non-attached core wire), it has no steerability or torqueability once the core wire is removed. Physicians may 25 desire to steer the distal end into another vessel after the infusion wire is already deployed. Without the ability to steer the tip, they often will be forced to withdraw the entire convertible wire, then place a regular guidewire at the desired site, follow it with an infusion catheter advanced over the guidewire, and then remove the regular guidewire and replace it with the infusion wire.

While the '636 patent discloses an integral core wire within the infusion lumen of 30 an infusion wire, the depicted embodiments all have at least one full length outer wire coil and a coaxial sheath leaving a small cross-section area for the infusion of infusate at slow, steady rates. A high pressure drop is effected along the length of the guidewire so

that the slow infusion rate between the distal coil wire turns and the infusion pressure is relatively insensitive to the fluid pressure of the fluid entering the lumen at the proximal end.

With respect to radiopaque markers, the '627 patent depicts a typical band shaped 5 marker that abuts the distal end of an inner sheath and lies over the continuous inner core wire. The band shaped marker causes a stiffening of the infusion wire body at that point. A further U.S. Patent No. 4,538,622 depicts a short radiopaque coil wound into the turns of a less radiopaque guidewire coil and the use of brazing to fill the coil turns and the gap with the core wire to hold it in place. The resulting mass is stiff and causes 10 the guidewire to be stiffer along the brazed length than adjacent proximal and distal lengths which in turn negatively affects guidewire performance.

An infusion wire with improved steerability and retaining a high infusion flow rate would therefore be a great improvement. Moreover, in infusion wires of the types described and in other guidewires and catheters, improved radiopaque markers that do 15 not increase the outer diameter or restrict the infusion lumen would also be a great improvement.

It is therefore a principal object of the present invention to provide an infusion guidewire of minimal outer diameter having an improved steerability while maximizing the unobstructed diameter of the infusion lumen and the flow rate of infusate.

20 It is a further object of the present invention to provide an improved radiopaque marker or markers incorporated into a guidewire or the like that minimizes any affect on the flexibility of the guidewire body, avoids increases in the guidewire outer diameter, and does not intrude into the infusion lumen thereof.

These and other objects of the invention are realized in a flexible elongated 25 medical infusion guidewire having proximal and distal portions between guidewire proximal and distal ends adapted for introduction through a selected path in a patient's body to a site in a blood vessel or body cavity and for infusing a drug or agent into the blood vessel or body cavity comprising: a flexible, elongated tubular, proximal inner sheath having an inner sheath lumen formed therein and a first length extending from the guidewire proximal end and distally through the proximal portion to a distal inner sheath 30 end; a flexible, elongated, helically wound, distal wire coil having a distal coil lumen formed therein and a second length extending from the guidewire distal end and

-5-

proximally through the distal portion to a proximal wire coil end thereof at a junction with the distal inner sheath end; an elongated, tubular outer sheath extending between the proximal and distal ends having an outer sheath lumen formed therein for receiving the proximal inner sheath in a proximal segment thereof and the distal wire coil in a 5 distal segment thereof such that the inner sheath lumen and the distal coil lumen are substantially co-axially aligned at the junction thereof and define an infusion lumen having an infusion diameter, the outer sheath having at least one infusion port formed therein in the distal segment thereof for allowing transmission of fluids between the infusion lumen, adjacent turns of the distal wire coil and the infusion port to the exterior 10 of the distal segment of the outer sheath; an elongated stiffening core wire having a proximal core wire end and a distal core wire end and an outer diameter smaller than the infusion diameter positioned within the infusion lumen to extend therein from the proximal end to the distal end of the outer sheath; means for attaching the distal core 15 wire end to the distal end of the distal wire coil within the outer sheath; and means for attaching the proximal core wire end to the proximal ends of the outer and inner tubular sheaths.

The infusion guidewire of the present invention provides enhanced handling advantages and infuse flow rates equal to or exceeding conventional infusion wires or convertible wires, while retaining the core wire in place. This allows the physician to 20 avoid removing and replacing the infusion guidewire with a regular guidewire as described above.

In infusion guidewires of the type having a distal wire coil, a radiopaque marker may be disposed in accordance with a further aspect of the present invention in coaxial alignment with the inner tubular sheath and the distal wire coil within the outer sheath 25 lumen. Preferably, the distal wire coil is formed with at least a plurality of spacings between adjacent coil turns thereof in at least a portion adjacent to the proximal wire coil end thereof, and the radiopaque means comprises a radiopaque wire coil having a plurality of coil turns and a further inner coil lumen formed therein, the plurality of coil turns disposed within a like plurality of the spacings between adjacent distal wire coil 30 turns such that the distal coil lumen and the further coil lumen are substantially co-axially aligned with the infusion lumen.

The coiled wire radiopaque marker is maintained in coaxial alignment with the

-6-

distal wire coil by pressure applied by the inner sheath and maintained in longitudinal alignment with the distal wire coil and the inner sheath by the outer sheath. The absence of solder or joint adhesive allows the coiled wire radiopaque marker, and the entire infusion guidewire, to flex where it is intertwined with the distal wire coil.

5 Other objects, advantages and features of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

10 FIG. 1 is a plan view of an infusion wire according to one embodiment of the present invention;

FIG. 2 is an end view of the proximal end of the infusion wire of FIG. 1;

FIG. 3 is an end cross-section view of the proximal end of the infusion wire of FIG. 1;

15 FIG. 4 is a partial cross-section plan view of an intermediate segment of the infusion wire of FIG. 1;

FIG. 5 is a partial cross-section plan view of the distal end segment of the infusion wire of FIG. 1; and

20 FIG. 6 is a partial cross-section plan view of a variation of the intermediate segment of the infusion wire of FIG. 1 including an integral radiopaque marker in accordance with a further aspect of the invention.

Turning now to FIGS. 1 - 5, they depict the construction of an infusion guidewire 10 in accordance with the preferred embodiment of the present invention incorporating the inventive infusion guidewire construction. The flexible elongated medical infusion guidewire 10 has proximal portion 12 and distal portion 14 between guidewire proximal end 16 and distal end 18 adapted for introduction through a selected path in a patient's body to a site in a blood vessel or body cavity and for infusing a drug or agent into the blood vessel or body cavity. Preferably, the overall usable length of the infusion guidewire 10 is on the order of 145 cm and an outer diameter of about 0.035 inches. The distal portion 14 preferably ranges from about 3.0 cm to about 20.0 cm.

As shown in FIGS. 1 - 3, the proximal portion 12 includes the luer connector housing 20 and the flexible, elongated, tubular, proximal inner sheath 24 of a first length

extending from the guidewire proximal end 16 and distally through the proximal portion 12 having an inner sheath lumen 30 formed thereby. The inner sheath 24 is preferably composed of a high strength, thin walled tubing, preferably polyimide, of 0.0295 inches in outer diameter and 0.0275 inches inner diameter, for example, that defines an inner 5 sheath lumen 30 therein. The proximal end of the polyimide inner sheath 24 is sealed within the lumen at one end of a strain relief 28 which is flared and compression fit at its other end between the male connector fitting 26 and a threaded female connector nut 32 threaded over it.

The polyimide inner sheath 24 extends distally through the proximal portion 12 to junction 36 with a proximal end of a flexible, elongated, helically wound, distal wire coil 40 of a second length extending to a distal wire coil end thereof at the guidewire distal end 18. The wire coil 40 preferably is formed of circular cross-section stainless 10 steel wire of about 0.004 inches diameter wound into a wire coil having an inner diameter of about 0.021 inches defining a wire coil infusion lumen 42 and an outer 15 diameter of about 0.029 inches. As shown in FIG. 4, the proximal end of the wire coil 40 is forced into the distal end inner sheath lumen 30 of the polyimide sheath 24.

Returning to FIG. 1, an elongated, tubular outer sheath 50 extends through the proximal and distal portions 12, 14 having an outer sheath lumen 52 formed therein for receiving the proximal inner sheath 24 in a proximal portion thereof and the distal wire coil 40 in a distal portion thereof. The inner sheath lumen 30 and the distal wire coil lumen 42 are substantially co-axially aligned at their junction 36 and define an infusion 20 lumen 34 having an infusion diameter that is stepped down slightly through and distally to junction 36. The outer sheath 50 provides a substantially constant outer diameter through the length of the infusion guidewire. The outer sheath 50 has at least one 25 infusion port 54, formed therein in the distal portion thereof for allowing transmission of fluids between the infusion lumen, adjacent enclosed turns of the distal wire coil 40 and the infusion port(s) 54, to the exterior of the distal portion of the outer sheath 50.

In order to allow the passage of infusate between the inner infusion lumen and the infusion port(s), the adjacent turns of the distal wire coil 40 are separated by 30 approximately one-half of wire diameter or about 0.002 inches. Preferably, the number n and the spacings apart of the infusion ports 54, may be selected as a function of the length of distal portion 14. For example, the number $n = 8$ for 3.0 cm length, $n = 14$

-8-

for 6.0 cm, $n = 20$ for 9.0 cm, and $n = 26$ for 12.0 cm.

The outer sheath 50 is preferably a Teflon (PTFE) shrink tube that can then be shrunken over the entire assembly of the inner polyimide sheath 24 and the distal wire coil 40 to lock the assembly in place and provide a lubricous outer surface. Prior to applying heat, the side holes or infusion ports 54_a are cut in or formed in the distal portion of the tube that will be shrunk over the separated turns of distal wire coil 40. At the polyimide inner sheath 24/wire coil 40 junction 36, the shrunken outer sheath 50 locks the assembly together with without the need for adhesives, braze, solder or the like, creating a flexible zone of junction 36.

An elongated stiffening core wire 56 having a proximal core wire end 58 and a distal core wire end 60 and an outer diameter smaller than the infusion diameter of the infusion lumen is also depicted in FIGS. 3 - 5. The stiffening core wire 56 is positioned within the aligned axial lumens 30 and 42 to extend between the proximal and distal ends 16, 18 of the guide wire 10. The integral stiffening core wire 56 preferably consists of a 0.016 inch diameter, stainless steel core wire which tapers to 0.0065 inches at the distal end 18. A continuous taper is commenced just proximal to the junction of inner polyimide sheath 24 and distal wire coil 40. Ideally, the .009" diameter portion of the taper is located at the most proximal portion end of the distal wire coil 40. The tapering provides a relatively constant cross-section area infusate passageway within the infusion lumen not occupied by the core wire 56, despite narrowing of the infusion lumen at and distally to the junction 36.

The integral core wire 56 is brazed at its distal core wire end 60 to the distal end of the distal wire coil 40 forming a braze ball 44 as shown in FIG. 5. The brazing creates the integral attachment of the core wire end 60 that provides for increased steerability and torque transfer. The core wire distal end 60 may be flattened prior to brazing in order to create a mechanical lock for a stronger braze pull force. The distal core wire end 60 and distal wire coil 40 can also be soldered or welded or attached with adhesive, but brazing is preferred. A platinum marker tube 46 made from a short length of platinum tubing is encapsulated in the braze ball 44 (or other attachment means) between the core wire 56 and the distal wire coil 40.

The braze ball 44 also serves to close the distal end of the infusion wire to internal infusate pressure. This is effected when the outer sheath 50 is heat shrunk. The

tip of the heat shrink tube sheath 50 is shrunk past the braze ball 44 to lock it in, and any remaining distal tail is trimmed short to about 0.015 inches in length.

5 The proximal end of core wire 56 is attached to the proximal luer connector housing 20 and thereby to the proximal ends of the inner and outer tubular sheaths 24 and 50. The attachment is in such a way that by torquing the connector housing 20, the distal core wire end 60 (and the distal end 18 of the guide wire 10) can be steered.

10 As shown in FIG. 3, the proximal core wire end 58 is bent into a shape which fits into a keyed groove 38 inside the connector housing 20. The connector housing 20 includes a hub member 62 having an outer surface 64 adapted to be manually engaged and manipulated to advance and rotate infusion guidewire 10 through a blood vessel.

15 The hub member 62 has an internal conduit 66 therein for transmission of infusion fluids to the infusion lumen 34 and for receiving the proximal core wire end 58. The proximal core wire end 58 is formed with a laterally bent shape in one plane of a size to prevent the bent shape from being advanced distally through the conduit 66 and the aligned infusion lumen 34 and for fixing the core wire 56 from rotation in the conduit 66 and the infusion lumen 34 during advancement and rotation of the infusion guidewire 10. A pair of planar side walls 68, 70 extend laterally on either side from the conduit 66 within the hub member 62 to form the cavity of the keyed groove 38 for receiving the bent shape of the proximal core wire end 58 and for restraining rotation thereof. The bent shape, proximal core wire end 58 can alternatively be insert molded into the proximal connector housing 20, leaving the conduit 66 open.

20 25 Rotational motion imparted to the hub member outer surface 64 is imparted to the core wire 56 and through the core wire 56 to the braze ball 44 attaching the distal core wire end 60 to the distal end of the distal wire coil 40 within the outer sheath 50. Because the distal end of the core wire 56 is brazed to the distal end of distal wire coil 40, the guidewire distal end 18 will be steerable. The core wire 56 can be shaped at the guidewire distal end 18 by the physician to improve the steerability.

30 The tapered core wire 56 within the infusion lumen 34 of the aligned proximal inner sheath and the distal wire coil an the integral attachment of its proximal and distal ends 58, 60 as described above replaces the full length wire coils of the side hole infusing guidewires of the above- referenced '627, and '636 patents. The resulting net cross-section area provides a flow lumen within the same outer diameter that allows a

-10-

flow rate exceeding or comparable to the flow rates of the side hole infusing guidewires of the '636 and '627 patents, respectively. For example, the flow rates for room temperature water at 100 psi are specified for the following differing infusate lengths:

5	3.0 cm	28 cc/min
	6.0 cm	30 cc/min
	9.0 cm	32 cc/min
	12.0 cm	34 cc/min

10 In use of the guidewire 10, both slow drip, i.e., weeping, infusion and spray infusion may be effected. The guidewire 10 is further specified to withstand pressures of up to 350 psi without bursting or tip leakage.

15 Turning to a further aspect of the present invention, current infusion guidewires (and other similar catheters) make use of high radiopacity radiopaque marker bands which are placed over a stainless steel coil or tubular sheath or the like and surrounded by PTFE shrink tubing. Alternatively, the marker bands are adhered, welded or brazed in line with a side wall coil or sheath or inside the lumen thereof. This layering procedure causes an increase in stiffness at the junction and either an increase in total outer diameter, or a decrease in inner lumen diameter.

20 In accordance with this aspect of the invention, as shown in FIG. 6, platinum spring marker wire coil 48, preferably made in the same 0.004 inch wire diameter and coiled with the same pitch, inside diameter and outside diameter as the distal wire coil 40, is screwed into the turns of the distal wire coil 40. The wire coils 40 and 48 are both wound in the same direction preferably with a gap of one-quarter to one times wire diameter. This allows the two coils to be screwed together preferably over a close fitting mandrel. The platinum marker wire coil 48 can be short (e.g. 0.050" long), and the coil turns need only to be wound together a few times to provide a good lock.

25 The two wire coils 48 and 40 are screwed together to form a high radiopacity marker of about 0.075 inches long. Both ends of the platinum marker wire coil 48 and a number of turns of the proximal end of the stainless steel distal wire coil 40 are forced into an interference fit within the distal end opening of inner sheath lumen 30. The inner sheath lumen 30 protects and holds the ends of the wire coil 48 turns from moving laterally, and maintains the diameter of the distal wire coil lumen 42 constant, and the outer sheath 50 prevents longitudinal displacement or separation of the intertwined coil

-11-

turns from the inner sheath lumen 30 without requiring an adhesive braze or solder. The platinum wire coil 48 turns at the proximal end of the stainless distal wire coil 40 thereby serve as a radiopaque marker to mark the proximal end of the infusion section.

As noted above, this aspect of the invention may alternatively be incorporated 5 into other known constructions of guidewires, infusion wires, convertible wires and catheters in substitution for the conventional radiopaque markers. Because the platinum wire coil is wound in an intertwined manner with the stainless wire coil, there is no reduction of a lumen diameter or increase in the outer diameter at the marker section. The resulting joint provides a radiopaque marker that can be readily seen under 10 fluoroscopy, yet which maintains the identical inner and outer diameter as a less radiopaque stainless steel coil and virtually the same flexibility without a marker. The resulting product has an outer surface with no bumps or increases in diameter and an inner lumen with no added restrictions to flow or to tracking over a guide wire.

While a number of preferred embodiments of the invention and variations thereof 15 have been described in detail, other modifications and methods of using and medical applications for the same will be apparent to those of skill in the art. Accordingly, it should be understood that various applications, modifications, and substitutions may be made of equivalents without departing from the spirit of the invention or the scope of the claims.

-12-

WHAT IS CLAIMED IS:

1. A flexible elongated medical infusion guidewire having proximal and distal portions between guidewire proximal and distal ends adapted for introduction through a selected path in a patient's body to a site in a blood vessel or body cavity and for infusing a drug or agent into the blood vessel or body cavity comprising:
 - 5 a flexible, elongated tubular, proximal inner sheath having an inner sheath lumen formed therein and a first length extending from said guidewire proximal end and distally through said proximal portion to a distal inner sheath end;
 - 10 a flexible, elongated, helically wound, distal wire coil having a distal coil lumen formed therein and a second length extending from said guidewire distal end and proximally through said distal portion to a proximal wire coil end thereof at a junction with said distal inner sheath end;
 - 15 an elongated, tubular outer sheath of substantially constant outer diameter extending between said proximal and distal ends having an outer sheath lumen formed therein for receiving said proximal inner sheath in a proximal portion thereof and for receiving said distal wire coil in a distal portion thereof such that said inner sheath lumen and said distal coil lumen are substantially co-axially aligned at said junction and define an infusion lumen having an infusion diameter, said outer sheath having at least one infusion port formed therein in said distal portion thereof for allowing transmission 20 of fluids between said infusion lumen, adjacent turns of said distal wire coil and said infusion port to the exterior of said distal portion of said outer sheath;
 - 25 an elongated stiffening core wire having a proximal core wire end and a distal core wire end positioned within said infusion lumen to extend therein from said proximal end to said distal end of said guidewire, said core wire having a first core wire section with a first outer core wire diameter smaller than said infusion diameter in said proximal portion, a second core wire section with a second core wire diameter smaller than said first core wire diameter in said distal portion and a third core wire section bridging said junction having a tapered core wire diameter between said first core wire diameter and said second core wire diameter;
 - 30 means for attaching said distal core wire end to said distal end of said distal wire coil at least partially within said outer sheath; and

-13-

means for coupling said proximal core wire end to said proximal ends of said outer and inner tubular sheaths and disposed within said infusion lumen for minimally obstructing said infusion lumen through the length of said infusion lumen.

2. The infusion guidewire of Claim 1 further comprising:
5 radiopaque means disposed in coaxial alignment with said inner tubular sheath and said distal wire coil within said outer sheath lumen.

3. The infusion guidewire of Claim 2 wherein:
said distal wire coil is formed with at least a plurality of spacings between adjacent coil turns thereof in at least a portion adjacent to said proximal wire coil end
10 thereof; and

15 said radiopaque means comprises a radiopaque wire coil having a plurality of coil turns and a further inner coil lumen formed therein, said plurality of coil turns disposed within a like plurality of the spacings between adjacent distal wire coil turns and maintained in coaxial alignment therewith such that said distal coil lumen and said further coil lumen are substantially co-axially aligned with said infusion lumen.

4. The infusion guidewire of Claim 3 wherein:
said means for attaching said distal core wire end to said distal end of said distal wire coil within said outer sheath comprises a closed end, ball braze.

5. The infusion guidewire of Claim 4 wherein said means for coupling said proximal core wire end to said proximal ends of said outer and inner tubular sheaths further comprises:
20

25 a hub member having an outer surface adapted to be engaged to advance and rotate said infusion guidewire through a blood vessel and a conduit therein for transmission of infusion fluids to said infusion lumen and for receiving said proximal core wire end;

core wire fixation means formed in said conduit for fixing said proximal core wire end from rotation in said conduit and in said infusion lumen during advancement and rotation of said infusion guidewire.

-14-

6. The infusion guidewire of Claim 5 wherein:

said core wire is formed with a bent shape in one plane at said proximal core wire end of a size to prevent said bent shape of said core wire from being advanced distally through said conduit and said aligned infusion lumen; and

5 said core wire fixation means further comprises
a pair of planar side walls extending from said conduit within said hub member to form
a cavity for receiving said bent shape of said core wire and for restraining rotation
thereof, whereby rotational motion imparted on said hub member is imparted to said
core wire and through said core wire to said means for attaching said distal core wire
10 end to said distal end of said distal wire coil within said outer sheath.

7. The infusion guidewire of Claim 1 wherein:

said means for attaching said distal core wire end to said distal end of said distal
wire coil within said outer sheath comprises a closed end, ball braze.

8. The infusion guidewire of Claim 7 wherein said means for coupling said
15 proximal core wire end to said proximal ends of said outer and inner tubular sheaths
further comprises:

a hub member having an outer surface adapted to be engaged to advance and
rotate said infusion guidewire through a blood vessel and a conduit therein for
transmission of infusion fluids to said infusion lumen and for receiving said proximal
20 core wire end;

core wire fixation means formed in said conduit for fixing said proximal core
wire end from rotation in said conduit and said infusion lumen during advancement and
rotation of said infusion guidewire.

9. The infusion guidewire of Claim 8 wherein:

25 said core wire is formed with a bent shape in one plane at said proximal core
wire end of a size to prevent said bent shape of said core wire from being advanced
distally through said conduit and said aligned infusion lumen; and

said core wire fixation means further comprises
a pair of planar side walls extending from said conduit within said hub member to form

-15-

a cavity for receiving said bent shape of said core wire and for restraining rotation thereof, whereby rotational motion imparted on said hub member is imparted to said core wire and through said core wire to said means for attaching said distal core wire end to said distal end of said distal wire coil within said outer sheath.

5 10. The infusion guidewire of Claim 1 wherein said means for coupling said proximal core wire end to said proximal ends of said outer and inner tubular sheaths further comprises:

10 a hub member having an outer surface adapted to be engaged to advance and rotate said infusion guidewire through a blood vessel and a conduit therein for transmission of infusion fluids to said infusion lumen and for receiving said proximal core wire end;

core wire fixation means formed in said conduit for fixing said proximal core wire end from rotation in said conduit and said infusion lumen during advancement and rotation of said infusion guidewire.

15 11. The infusion guidewire of Claim 10 wherein:

said core wire is formed with a bent shape in one plane at said proximal core wire end of a size to prevent said bent shape of said core wire from being advanced distally through said conduit and said aligned infusion lumen; and

10 said core wire fixation means further comprises
a pair of planar side walls extending from said conduit within said hub member to form a cavity for receiving said bent shape of said core wire and for restraining rotation thereof, whereby rotational motion imparted on said hub member is imparted to said core wire and through said core wire to said means for attaching said distal core wire end to said distal end of said distal wire coil within said outer sheath.

25 12. In a flexible elongated medical device of the type formed of a first flexible, elongated, helically wound, wire coil of a predetermined length and having a first inner coil lumen formed therein, the improvement in a radiopaque marker comprising:

a plurality of spacings between a plurality of adjacent coil turns formed in at least

-16-

a portion of said first wire coil;

a second radiopaque wire coil of a material having a higher radiopacity than said first wire coil formed into a plurality of radiopaque wire coil turns and having a second inner coil lumen formed therein;

5 means for disposing said plurality of radiopaque wire coil turns intertwined within said plurality of spacings between adjacent wire coil turns of said first wire coil; and

means for maintaining said first and second wire coils substantially co-axially aligned and said first and second inner coil lumens substantially unrestricted.

10 13. The medical device of Claim 12 wherein said first and second wire coils are wound in wire coil turns having substantially the same outer coil diameter and inner coil diameter.

14. The medical device of Claim 13 wherein said maintaining means further comprises sheath means having an inner lumen for receiving and contacting the outer 15 diameters of said first and second coil wires and applying compressive force thereto.

15. The medical device of Claim 12 wherein said maintaining means further comprises sheath means having an inner lumen for receiving and contacting the outer diameters of said first and second coil wires and applying compressive force thereto.

16. A method of fabricating a flexible elongated medical device of the type 20 formed of a first flexible, elongated, helically wound, wire coil of a predetermined length and having a first inner coil lumen formed therein with a radiopaque marker comprising the steps of:

forming a plurality of spacings between a plurality of adjacent coil turns in at least a portion of said first wire coil;

25 forming a second radiopaque wire coil of a material having a higher radiopacity than said first wire coil with a plurality of radiopaque wire coil turns having a second inner coil lumen;

disposing said plurality of radiopaque wire coil turns within said plurality of

-17-

spacings between adjacent wire coil turns of said first wire coil such that said first and second wire coils and inner coil lumens are substantially co-axially aligned; and

maintaining said first and second wire coils substantially co-axially aligned and said first and second inner coil lumens substantially unrestricted.

5 17. The method of Claim 16 further comprising the step of winding said first and second wire coils in wire coil turns having substantially the same outer diameter and inner coil lumen diameter.

10 18. The method of Claim 17 wherein said maintaining step further comprises inserting said co-axially aligned first and second wire coils into an inner lumen of an outer sheath for thereby applying compressive force to the outer diameters thereof.

19. The method of Claim 16 wherein said maintaining step further comprises inserting said co-axially aligned first and second wire coils into an inner lumen of an outer sheath for thereby applying compressive force to the outer diameters thereof.

1/2

Fig. 1

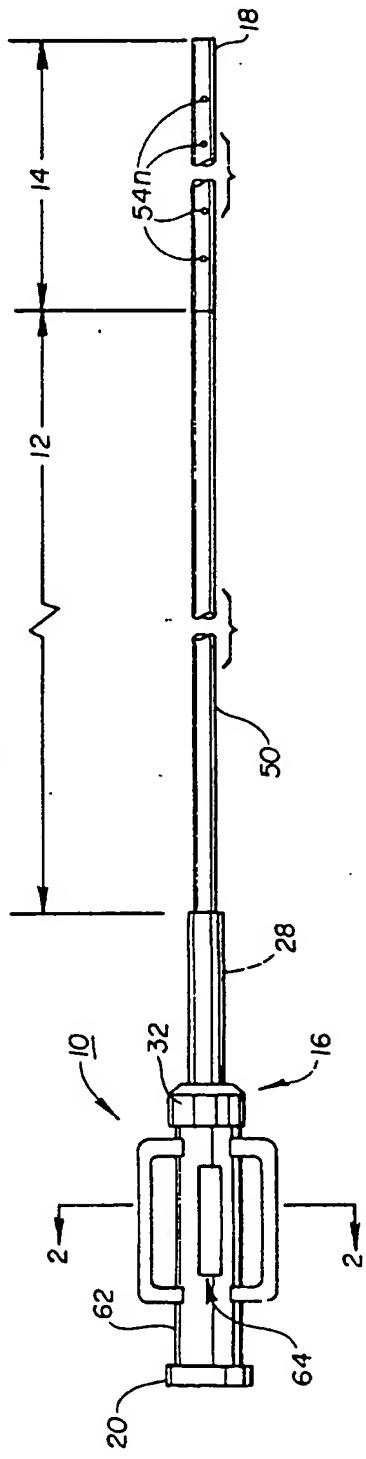
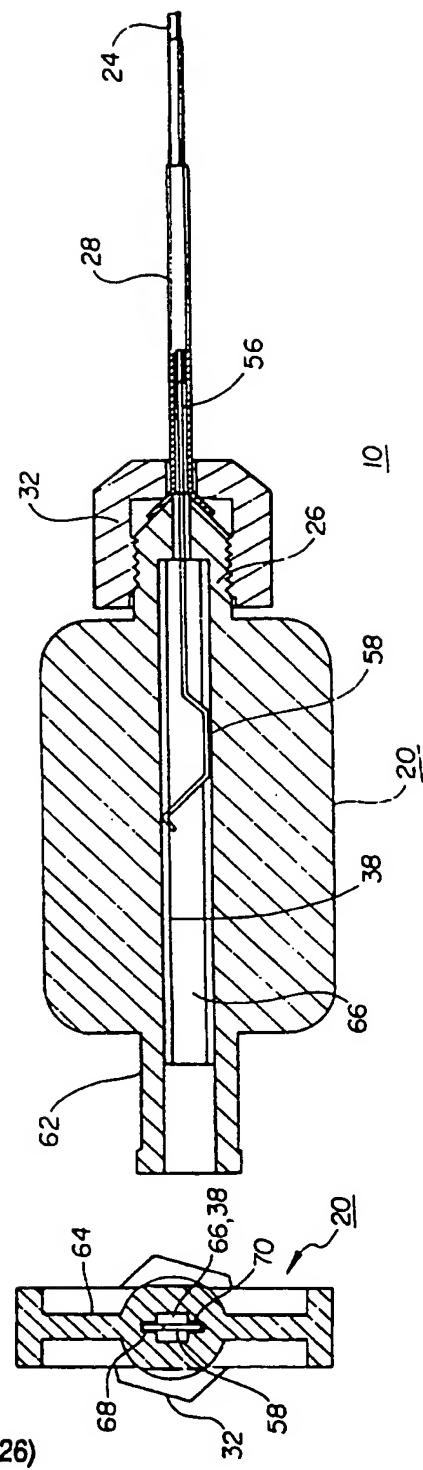


Fig. 2

SUBSTITUTE SHEET (RULE 26)

Fig. 3



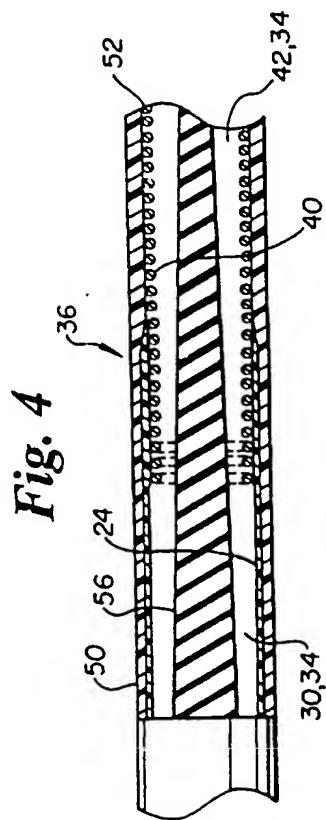
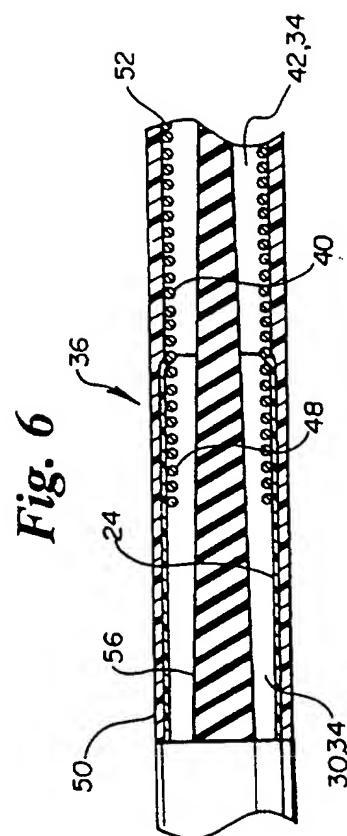
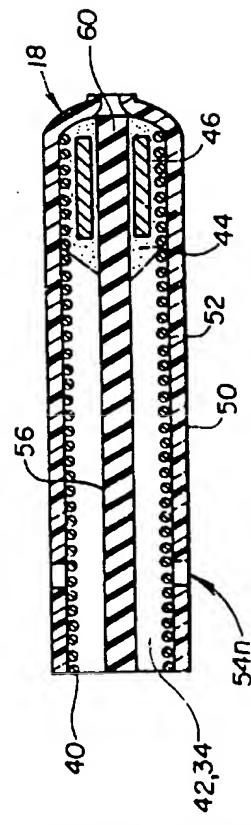


Fig. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/16004

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00

US CL :128/657, 658, 772; 604/95.06, 280-283

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/657,658, 772; 604/95.06, 280-283

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,184,627 A (DE TOLEDO) 09 February 1993, col. 2, lines 34-42; and Fig. 2.	1-8
Y	US 4,917,104 A (REBELL) 17 April 1990, col. 1, lines 25-35.	1
Y	US 5,174,302 A (PALMER) 29 December 1992, col.4, lines 17-28.	3
Y	US 5,211,636 A (MISCHE) 18 May 1993, cols. 2 and 3.	1, 4-8

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A	document defining the general state of the art which is not considered to be of particular relevance	
E	earlier document published on or after the international filing date	*X*
L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
O	document referring to an oral disclosure, use, exhibition or other means	*Y*
P	document published prior to the international filing date but later than the priority date claimed	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
	&	document member of the same patent family

Date of the actual completion of the international search

14 JANUARY 1997

Date of mailing of the international search report

03 FEB 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Faxsimile No. (703) 305-3590

Authorized officer *P. M. Wingood*
PAMELA WINGOOD
Telephone No. (703) 308-2676